Citation:

Behall KM, Scholfield DJ, Hallfrisch J. Whole-grain diets reduce blood pressure in mildly hypercholesterolemic men and women. *J Am Diet Assoc.* 2006 Sep; 106(9): 1,445-1,449.

PubMed ID: 16963350

Study Design:

Non-Randomized Crossover Trial

Class:

A - Click here for explanation of classification scheme.

Research Design and Implementation Rating:

POSITIVE: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

To examine the effects on blood pressure in mildly hypercholesterolemic men and women consuming controlled whole-grain diets containing brown rice, whole wheat, and barley.

Inclusion Criteria:

Healthy men and women with blood pressure less than 140mm Hg systolic and less than 90mm Hg diastolic and cholesterol levels 200 to 240mg per dL.

Exclusion Criteria:

- Substantial weight change in the previous six months
- Taking medication known to affect blood pressure, lipids or glucose.

Description of Study Protocol:

Design

Non-randomized crossover trial.

Dietary Intake/Dietary Assessment Methodology

Subjects discontinued all vitamins and supplements and agreed to consume only those foods presented to them or approved by the investigators. All foods were prepared and weighed to the nearest 0.5 g at the study facility.

Intervention

- Subjects consumed the Step I American Heart Association (AHA) diet with a seven-day rotating menu for the first two weeks

- The three diets listed below were consumed for five weeks each. An equal number of participants consumed each diet during each period and all subjects consumed all diets. Whole-grain diets contained 0 to 2.2g per 1,000kcal soluble fiber form barley and 9.7 to 11.9g per 1,000kcal total dietary fiber.
    - Barley
    - Whole wheat or brown rice
    - Half barley and half whole wheat or brown rice.

Statistical Analysis

- Date were analyzed using mixed procedure analysis of variance
- Subjects were their own controls.

Data Collection Summary:

Timing of Measurements

- Weekly after breakfast, blood pressure was taken at the study facility
- 24-hour complete urine samples were collected during the last three days of each period.

Dependent Variables

- Blood pressure (systolic - SBP, diastolic - DBP): Measured at study facility
- Mean arterial blood pressure: Calculated as 2/3 [(systolic pressure/2) + (diastolic pressure)].

Independent Variables

Diets:

- Step I American Heart Association
- Barley
- Whole wheat or brown rice
- Half barley and half whole wheat or brown rice.

Description of Actual Data Sample:

- *Initial N:* 27
- *Attrition (final N):* 25 (seven men, nine pre-menopausal women, nine post-menopausal women)
- *Mean age:* (SE)
    - 43 years (five) for men
    - 47 years (four) for pre-menopausal women
    - 50 years (three) for post-menopausal women
- *Location:* United States.

Summary of Results:

Key Findings

- Consumption of all whole-grain diets resulted in decreases in blood pressure (SBP, $P<0.021$; DBP, $P<0.009$; mean arterial pressure, $P<0.050$)

- Systolic blood pressure declined 2.2mmHg (NS) while subjects consumed the Step I diet and an additional 1.4 to 6.7mmHg while subjects consumed the whole-grain diets
- Diastolic blood pressure declined 2mmHg (NS) while subjects consumed the Step I diet and an additional 2.9 to 3.7mmHg while subjects consumed the whole grain diets.

Mean (± Standard Error of the Mean) of Weekly Blood Pressures of Mildly Hypercholesterolemic Mena and Women Initially and After Consuming Whole Grain Diets

Variables	Initial	Step I	Whole Wheat or Brown Rice	Half-and-half	Barley
Systolic blood pressure (mmHg)	117.6 (2.4)^{x}	115.4 (2.4)^{xy}	110.2 (2.4)^{y}	108.7 (2.4)^{y}	114.0 (2.4)^{xy}
Diastolic blood pressure (mmHg)	71.0 (1.6)^{x}	69.0 (1.7)^{x}	65.3 (1.7)^{y}	65.8 (1.7)^{y}	66.1 (1.7)^{y}

^{xy}Means within a row with different superscripts are significantly different ($P<0.05$) based on least squares mean.

Other Findings

- For men, mean arterial pressure declined significantly compared to baseline while consuming the half-and-half diet (10.8mmHg, $P<0.05$)
- For pre-menopausal women, mean arterial pressure declined significantly compared to baseline while consuming the Step I, half-and-half, and barley diets (10.8mmHg, $P<0.05$)
- For post-menopausal women, mean arterial pressure declined significantly compared to baseline while consuming the barley diet (9.0mmHg, $P<0.05$)
- Subjects lost about 1kg during the study ($P<0.01$).

Author Conclusion:

Consumption of a healthy diet high in fiber from whole-grain foods lowers systolic and diastolic blood pressure in mildly hypercholesterolemic men and women whether sources are barley (soluble fiber), whole wheat and brown rice (insoluble fiber) or a combination of these whole-grain foods.

Reviewer Comments:

- *Study strengths:*
  - *24-hour complete urine samples were collected to assure that there was no variation in minerals or dietary factors that might affect blood pressure or indicate non-compliance. Mean mineral excretion did not vary by period*
  - *Duplicate blood pressure readings were taken*
- *Study limitations:*
  - *Small sample size*
  - *Amount of participation in physical activity was not collected throughout the study, and subjects lost weight (about 1kg) during the study.*

Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions

1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)	Yes
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes
3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?	Yes
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes

Validity Questions

1.	**Was the research question clearly stated?**	Yes
1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes
1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes
1.3.	Were the target population and setting specified?	Yes
2.	**Was the selection of study subjects/patients free from bias?**	Yes
2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	Yes
2.2.	Were criteria applied equally to all study groups?	Yes
2.3.	Were health, demographics, and other characteristics of subjects described?	Yes
2.4.	Were the subjects/patients a representative sample of the relevant population?	???
3.	**Were study groups comparable?**	N/A
3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	N/A
3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	N/A
3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	N/A

3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	N/A
3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A
3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	**Was method of handling withdrawals described?**	Yes
4.1.	Were follow-up methods described and the same for all groups?	Yes
4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	Yes
4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	Yes
4.4.	Were reasons for withdrawals similar across groups?	N/A
4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
5.	**Was blinding used to prevent introduction of bias?**	???
5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	???
5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	???
5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	N/A
5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.	**Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were interveningfactors described?**	Yes
6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	Yes
6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	N/A

6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	???
6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	Yes
6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	N/A
6.6.	Were extra or unplanned treatments described?	N/A
6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	Yes
6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
7.	**Were outcomes clearly defined and the measurements valid and reliable?**	Yes
7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes
7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	Yes
7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes
7.5.	Was the measurement of effect at an appropriate level of precision?	Yes
7.6.	Were other factors accounted for (measured) that could affect outcomes?	N/A
7.7.	Were the measurements conducted consistently across groups?	Yes
8.	**Was the statistical analysis appropriate for the study design and type of outcome indicators?**	Yes
8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes
8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes
8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes
8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	???
8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	N/A
8.6.	Was clinical significance as well as statistical significance reported?	No

8.7.	If negative findings, was a power calculation reported to address type 2 error?	N/A
9.	**Are conclusions supported by results with biases and limitations taken into consideration?**	???
9.1.	Is there a discussion of findings?	Yes
9.2.	Are biases and study limitations identified and discussed?	???
10.	**Is bias due to study's funding or sponsorship unlikely?**	Yes
10.1.	Were sources of funding and investigators' affiliations described?	Yes
10.2.	Was the study free from apparent conflict of interest?	Yes